DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N–0220]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Substances Approved for Use in the Preparation of Meat and Poultry Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Petition for Approval of Substances for Use in the Preparation of Meat and Poultry Products—21 CFR 71.1 and 171.1

Sections 409 and 721 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 348 and 379e) require FDA to evaluate the safety and regulate the use of food and color additives used as ingredients in or on all foods. These sections also authorize FDA to accept petitions for approval of food and color additives. The Federal Meat Inspection Act and the Poultry Products Inspection Act (21 U.S.C. 601(m)(2) and 453(g)(2), respectively) authorize the administration of the Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture to determine the suitability of the use of a substance in meat and poultry products. Regulations of the two agencies regarding petition submissions at times include conditions, formats, and terms that are not fully consistent with one another because of the different statutory mandates. Under the current process, FDA and FSIS conduct separate, sequential reviews of petitions, each agency applying its respective procedures to ascertain that a substance is lawful for the use intended in or on products containing meat or poultry.

When petitioning for approval for the use of substances in meat and poultry products, the applicants must provide four copies of the petition to FDA, rather than the three copies as currently specified in §§ 71.1 and 171.1 (21 CFR 71.1 and 171.1). FDA will then forward a copy of the petition or relevant portions of the petition to FSIS so that both agencies can perform the necessary reviews simultaneously, thus reducing the time it takes to authorize an ingredient for use in meat and poultry products. The petitioners are not required to submit any new information to either FDA or FSIS.

This regulation results from a coordinated effort by the two agencies to ease the paperwork burden on regulated industries through streamlining the Federal Government's food ingredient approval process for substances used in meat and poultry products.

Description of Respondents: Businesses or other for profit.

In the **Federal Register** of August 25, 2000 (65 FR 51758), the agency requested comments on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL INCREASE IN REPORTING HOUR BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Increase in Hours per Response	Total Increase in Hours
71.1 and 171.1	10	1	10	2	20

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA's past experience with food and color additive petitions and on discussions with FSIS about its past experience, it will receive 10 petitions annually that request approval for use of a substance in meat and poultry products. Submission of a petition for the use of a substance in meat and poultry products is a one-time event. FDA estimates that the respondent would expend 2 hours to make a fourth photocopy of the petition, necessary for FDA to send

to FSIS to conduct a simultaneous review. FDA, therefore, estimates that the total burden of data collection under §§ 71.1 and 171.1 will increase by 20 hours per year because of the requirement to submit a fourth copy of petitions when a substance is to be used in meat or poultry products.

Dated: November 20, 2000

Margaret M. Dotzel
Associate Commissioner for Policy

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